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Atty. Docket No. 249/146US

**REMARKS**

With this response the specification has been amended to address some of the objections raised in the Office Action. The amendments to the specification are fully supported by the specification as filed and so no new matter has been added. With this response claims 1-42 have been cancelled without prejudice to pursue the subject matter of these claims in a related application, and new claims 84 to 125 have been added. The new claims are fully supported by the application as filed. Claims 43-83 were previously withdrawn from consideration. Thus, the claims currently under examination are 84-125. The cancellation of claims 1-42 should not be taken as Applicants acquiescence in the rejections of these claims put forth in the office action of May 19, 2004. Cancellation of claims 1-42 and addition of claims 84-125 has been done simply to speed prosecution in anticipation of the commercialization of a product that is the subject of new claims 84-125. As detailed below, Applicants are of the opinion that the subject matter of cancelled claims 1-42 is fully patentable and Applicants intend to pursue said subject matter in a related application

**Objections**

In the Office Action, the Examiner requested that "GLP-1" at line 26 of page 2; "ICV" at line 19 of page 6; and "RP-HPLC" at line 27 of page 60 be spelled out in full. Applicants respectfully submit that these abbreviations are commonly used in the art and that their meaning is well known. Without agreeing with the objections, but to speed prosecution, Applicants have amended the specification as suggested by the Examiner.

In the Office Action, the use of "at 0 weeks" at line 28 of page 21 was objected to and it was requested that it be replaced with "at 0 week." Applicants respectfully submit that 0 weeks is the proper English usage. When used as an adjective, zero modifies a plural noun. *Garner's Modern American Usage*, Bryan A. Garner, Oxford University Press, 2003. Withdrawal of this objection is, therefore, respectfully requested.

In the Office Action it was suggested that "SEQ. ID. NOS." in the specification be amended to "SEQ. ID. NOs." Applicants have considered this suggestion, but respectfully decline. The MPEP and related regulations require only that sequences be

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identified in the text by sequence identification number. There is no requirement as to whether a capital or lower case S is used. Since this objection appears to reflect a preference rather than a formal requirement, Applicants respectfully request reconsideration and withdrawal of this objection.

In the Office Action, it was suggested that "1  $\mu$ g - 30  $\mu$ g" at line 28 of page 51 be amended to "1-30  $\mu$ g" for consistency. Without acquiescing in the grounds for the objection, but to speed prosecution, Applicants have amended the specification as suggested in the Office Action.

In the Office Action, it was suggested that "body wt." at line 24 or page 57 be amended to "body weight." Applicants submit that "wt." is a well-established abbreviation for weight. In order to speed prosecution, however, the specification has been amended as suggested in the Office Action.

In the Office Action, it was asserted that the use of "(GLP-1)" immediately after "GLP-1 [7-36]NH<sub>2</sub>" introduced ambiguity. Applicants respectfully submit that when the paragraph is read as a whole, no ambiguity exists. Rather, the use of "(GLP-1)" immediately after "GLP-1[7-36]NH<sub>2</sub>" simply indicates that for Examples A to E that GLP-1[7-36]NH<sub>2</sub> has been shortened to GLP-1. This is confirmed by the text at lines 27-30 on page 2 of the specification. The use of parentheticals to indicate a shortening of a word or other indicator is commonly used in scientific and legal writing and would be readily understood by one skilled in the art, especially when read in light of the specification. Applicants respectfully request withdrawal of this objection.

#### **Non Art Based Rejections**

##### **Rejections Under 35 U.S.C. 112.**

In the Office Action, claims 7, 9 and 12-42 were rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With this amendment, claims 1-42 have been cancelled thus obviating all the rejections under 35 U.S.C. 112. Applicants submit, however, that the terms "0.9% saline" and "bulking agent", which were the bases for the rejection claims 26 and 29, are

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well known and commonly used in the art. Moreover, when read in light of the specification as a whole, Applicants contend that what was claimed would be understood by one of ordinary skill in the art

### Art Based Rejections

#### Rejections Under 35 U.S.C. 102

Applicants acknowledge that no claims were rejected under 35 U.S.C. 102 in the Office Action of May 19, 2004.

#### Rejections Under 35 U.S.C. 103

In the Office action claims 1-5, 8, 10-12 and 28-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hiles et al. (U.S. Patent No. 6,506,724). With the cancellation of claims 1-42, the rejection of claim 1-5, 8, 10-12 and 28-31 is obviated. Since the same elements that were present in the cancelled claims are also present in newly added claims 84-125, Applicants will address these rejections in order to speed prosecution.

In particular, Hiles et al. are relied upon to teach or suggest the use of an exendin or exendin agonists in pharmaceutical formulations and the use in these formulations of, acetate/acetic acid buffers, mannitol as an isotonicity modifier, a pH ranging from 3 to 7, a liquid formulation, a concentration of exendin within the range of 0.005% to 0.4%, polyethylene glycol, lactose, a solid formulation, and surfactants. Applicants respectfully wish to point out that each of these claim elements can be found in U.S. Provisional Application Serial No. 60/116,380, filed January 14, 1999, to which the present application claims priority. The earliest priority date for Hiles et al. is June 1, 1999. It is axiomatic in patent law that a reference with a priority date later than the present application cannot serve as a reference under 35 U.S.C. 103. Applicants therefore submit that Hiles et al. is an improper reference and respectfully request reconsideration and withdrawal of all rejections under 35 U.S.C. 103 based upon Hiles et al.

In the Office Action, claims 1, 2, 6, 12, 13 and 28-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Larson et al. (U.S. Patent No. 6,528,486). In

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view of the cancellation of claims 1-42, the grounds for these rejections are obviated. However, since the same issues are relevant to newly added claims 84-125, Applicants will address the grounds for the rejections in order to speed prosecution.

In particular, Larson et al. are relied upon to teach or suggest exendin formulations containing an acetate buffer, a preservative, polyethylene glycol, a surfactant; as well as liquid, lyophilized and multi-dose preparations. As with the rejections discussed above, all of these claim elements can be found in U.S. Provisional Patent Application Serial No. 60/116,380, filed January 14, 1999, which serves as a priority document for the present application. The earliest priority date for Larson et al. is July 12, 1999. Because the present application has an earlier priority date than does Larson et al., Applicants submit that Larson et al. cannot serve to render the present invention obvious under 35 U.S.C. 103. Applicants, therefore, respectfully request reconsideration and withdrawal of all rejection based upon Larson et al.

### **Conclusion**

In light of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of all objections and rejections set forth in the Office action of May 19, 2004. Further, Applicant respectfully submits that all claims presently under consideration are in a condition for allowance and requests issuance of a Notice of Allowance at the Examiner's earliest convenience.

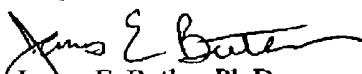
Should the Examiner have any remaining questions regarding the subject invention or its patentability, Applicant encourages the Examiner to contact the undersigned to answer such questions or provide additional information.

Applicants believe that no fee is due in association with this response. If the Applicants are in error, the Commissioner is hereby authorized to charge any underpayment or credit any overpayment that may occur during the pendency of this application to Deposit Account No. 01-0535.

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Respectfully submitted,



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**Certificate of Transmission Under 37 C.F.R. 1.8**

I hereby certify that the following listed correspondence in the above referenced application is being transmitted by facsimile to the Commissioner for Patents, Washington DC to telephone number (703) 872-9306 on this 20th day of July, 2004.



Amanda Halverson  
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